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10/599,708	07/27/2007	Heping Huang	3557.2.123	3051

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MADSON & AUSTIN
15 WEST SOUTH TEMPLE
SUITE 900
SALT LAKE CITY, UT 84101

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	PAPER NUMBER
3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,708	HUANG ET AL.	
	Examiner	Art Unit	
	ADAM MARCETICH	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. China 200420021636.6, filed on 06 April 2004 has been received.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809) in view of Cham (US Patent 4,895,558), further in view of Jacobsen (US Patent 5,141,493).

5. Regarding claim 9, Bomberger discloses an in-vitro blood plasma lipids screening procedure comprising:

a blood collecting device (¶ [0108] and Fig. 2, fluid source 28),

a blood separating device (¶ [0093], [0114] and Fig. 2, centrifuge 86),

a blood lipids screening procedure (¶ [0111], [0112], DTCs (drip through column) 44 and 46 removing lipids),

a blood plasma feedback device (¶ [0093] and Fig. 1, blood cells returned to patient),

which are connected via tubes (Fig. 2, tubes throughout system 10), and

the tubes being also connected with a peristaltic pump (¶ [0108] and Fig. 2, peristaltic pump 30),

pressure and temperature control devices being installed among the tubes (¶ [0115] and Fig. 2, sensors 96).

Bomberger discloses the invention as substantially claimed, see above. However, Bomberger lacks pre- and post-filtered blood plasma bags, a saline solution treatment bag and a waste saline solution bag as claimed [claim 9]. Cham discloses:

a saline solution treatment bag (column 8, lines 40-44 and Fig. 6, replacement fluid solution container), and

a waste saline solution bag (column 8, lines 8-18 and Fig. 6, waste bag),

Cham provides the advantage of storing waste fluid for later disposal or analysis, and replacing fluid lost to a filtering process. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger as discussed with the saline solution treatment bag and waste saline solution bag as taught by Cham in order to store waste fluid and replace lost fluid.

Bomberger in view of Cham discloses the invention as substantially claimed, see above. However, Bomberger in view of Cham lacks pre- and post-filtered blood plasma bags, as claimed [claim 9]. Jacobsen discloses a blood filtering system comprising a filter and peristaltic pumps. Jacobsen discloses:

a pre-filtered blood plasma container (column 3, lines 21-34 and Fig. 1A, bubble trap 20; Examiner notes that providing a bag in place of a rigid container is commonly practiced in the art), and

a post-filtered blood plasma bag (column 3, lines 43-54 and Fig. 1A, 3-liter bag 48).

It is the Examiner's position that motivation exists to connect the saline solution treatment bag to an outlet of the pre-filtered blood plasma container in order to pass fluid through a dialyzer for purification as depicted in Fig. 1A of Jacobsen.

It is the Examiner's position that motivation exists to connect the waste saline solution bag to an entrance of the post-filtered blood plasma bag of Jacobsen in order to provide the advantage of maintaining a measurement of dialysate (column 5, lines 9-13 and Fig. 1A, load sensor 52).

6. Regarding claim 10, Bomberger in view of Cham discloses the invention as substantially claimed, see above. However, Bomberger in view of Cham lacks an automatic weight/volume detection device as claimed [claim 10]. Jacobsen discloses sensors for detecting pressure, volume and/or weight (column 5, lines 9-13 and Fig. 1, load sensor 52; lines 14-26, pressure sensor 76 and column 6, lines 2-16, load sensor 180). Pressure sensor 76 operates to signal pump 72 to stop in response to pressure

exceeding a safe level (column 5, lines 20-26). Examiner notes that controlling a blood processing system to stop treatment when a container has been filled or emptied during the course of treatment is within the scope of obviousness, since it indicates a condition where a clog or obstruction may be in the fluid circuit. Specifically, stopping a blood treatment process when bubble trap 20 of Jacobsen is full would prevent potentially hazardous pressure buildup. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger in view of Cham as discussed with the automatic detection devices as taught by Jacobsen in order to prevent potentially hazardous pressure buildup.

7. Regarding claim 11, Bomberger in view of Cham in view of Jacobsen discloses the invention as substantially claimed, see above. However, Jacobsen is silent to the specific volume of bubble trap device 20 to be about 150-250 ml. However, this volume is deemed to be a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Thus, it would have been obvious to one of ordinary skill in the art to modify the volume as claimed as a mere design choice lacking any criticality of value as being merely preferable for the intended purpose of storing fluid before processing, as a buffer. In other words, setting a buffer volume is subject to the speed at which plasma can be treated.

Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device

was not patentably distinct from the prior art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

8. Regarding claim 12, Bomberger discloses an in-vitro blood plasma lipids screening procedure wherein a pressure control device reads out a current pressure inside the tube (¶ [0115], [0126]; Fig. 2, sensors 96 and Fig. 9, pressure sensors 146, 154 and 156). Examiner notes that the language "reads out" is interpreted broadly to include communicating with a processor or controller.

9. Regarding claim 13, Bomberger discloses an in-vitro blood plasma lipids screening procedure wherein blood plasma passes to the screening procedure at a speed of 20-30 milliliters per minute (¶ [0124], plasma flow rate between about 10-60 mL per minute).

10. Regarding claim 14, Bomberger in view of Cham in view of Jacobsen discloses the invention as substantially claimed, see above. Bomberger discloses pressure sensors 146, 154 and 156 as discussed above. However, Bomberger is silent to the specific pressure of the system being controlled to remain below 60 kPa. However this pressure is deemed a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Thus, it would have been obvious to one of ordinary skill in the art to modify the system pressure as claimed as a mere design choice lacking any criticality of value as being merely preferable for the intended purpose of preventing a patient from being exposed

to unsafe pressure levels. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. Regarding claim 15, Bomberger discloses an in-vitro blood plasma lipids screening procedure wherein a temperature control device is installed in the screening procedure (¶ [0115], sensors 96 for monitoring temperature). Examiner notes that the language "installed in the screening procedure" is interpreted broadly to include the system of Bomberger comprising a temperature sensor.

12. Regarding claim 16, Bomberger in view of Cham in view of Jacobsen discloses the invention as substantially claimed, see above. Bomberger discloses sensors 96 for monitoring temperature as discussed above. However, Bomberger is silent to the specific temperature of the system being controlled to remain below 38C. However this temperature is deemed a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Thus, it would have been obvious to one of ordinary skill in the art to modify the system temperature as claimed as a mere design choice lacking any criticality of value as being merely preferable for the intended purpose of preventing blood from being exposed to unsafe pressure levels. In other words, blood cells may be damaged by high

temperatures, and limiting a system temperature prevents hemolysis. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

13. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809) in view of Cham (US Patent 4,895,558) in view of Jacobsen (US Patent 5,141,493), further in view of Matkovich et al. (US Patent 5,252,222).

14. Regarding claim 17, Bomberger discloses an in-vitro blood plasma lipids screening procedure wherein a first film is a membrane which has filter aperture pore of about 0.3 to 0.65 microns and comprises a lipid absorptive material (¶ [0101]-[0102] and Fig. 3, HFC 18 comprising hollow fibers 20 having pores 26 sized up to 300 nm, or 0.3 μm). Hollow fibers are substantially lipid absorptive, as indicated by their ability to allow lipids to diffuse through pores 26.

Bomberger in view of Cham in view of Jacobsen discloses the invention as substantially claimed, see above. However, Bomberger in view of Cham in view of

Jacobsen lacks second and third films as claimed [claim 17]. Matkovich discloses a filter for treating parenteral fluids (column 3, lines 16-19) comprising:

a second film membrane having a filter aperture pore of about 0.3 microns (column 8, lines 32-41 and column 7, lines 54-58, prefilter in examples 3 and 5 having pore rating of about 2 μm. It is the Examiner's position that the prefilter of Matkovich substantially approximates the claimed range of about 0.3 μm.), and

a third film membrane having a filter aperture pore of about 0.2 microns that is made of nylon as a base material (column 8, lines 32-41, hydrophilic nylon membrane with pore rating of about 0.65 μm).

Matkovich provides the advantages of removing particulate matter and microorganisms from a lipid-containing liquid (column 2, lines 25-36 and 39-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger in view of Cham in view of Jacobsen as discussed with the second and third film membranes as taught by Matkovich in order to remove particulate matter or microorganisms.

15. Regarding claim 18, Bomberger in view of Cham in view of Jacobsen discloses the invention as substantially claimed, see above. However, Bomberger in view of Cham in view of Jacobsen lacks second and third films as claimed [claim 18]. Matkovich discloses second and third films as discussed above. Matkovich discloses a second film as a "prefilter" (column 7, lines 54-58). Therefore, it is the Examiner's position that adding the limitations of second and third filters as taught by Matkovich would place the first film as taught by Bomberger between second and third filters of Matkovich.

Matkovich provides the advantage of removing particulate matter and microorganisms from a lipid-containing liquid as discussed for claim 17 above. These materials may clog a lipid-filtering layer as taught by Bomberger; therefore Matkovich also provides the advantage of allowing a lipid-filtering layer to only remove lipids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger in view of Cham in view of Jacobsen as discussed by interposing the first film as taught by Bomberger between second and third films of Matkovich in order to promote effectiveness of a lipid-filtering layer.

16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809) in view of Cham (US Patent 4,895,558) in view of Jacobsen (US Patent 5,141,493) in view of Matkovich et al. (US Patent 5,252,222), further in view of Foltz et al. (US Patent 5,401,466).

17. Regarding claim 19, Bomberger in view of Cham in view of Jacobsen in view of Matkovich discloses the invention as substantially claimed, see above. However, Bomberger in view of Cham in view of Jacobsen in view of Matkovich lacks silicon oxide pellets as claimed [claim 19]. Matkovich discloses a separation device for lipids (column 3, lines 27-34), comprising a lipid absorptive material comprising silicon oxide pellets (column 6, lines 25-44, especially lines 32-36). Matkovich provides the advantage of removing very low density lipoproteins (VLDL) from blood (col. 3, lines 34-41).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger in view of Cham in view of Jacobsen in view of Matkovich as discussed with the silicon oxide pellets as taught by Matkovich in order to remove VLDL from blood.

18. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809).

19. Regarding claim 1, Bomberger discloses a blood plasma lipids in-vitro filtering method, comprising the following steps:

separating blood plasma from collected blood (¶ [0093], [0114] and Fig. 2, centrifuge 86 separating blood plasma);

carrying out flushing (¶ [0092], flushing HFC / hollow fiber contactor);

controlling temperature and pressure of the blood plasma (¶ [0115] and Fig. 2, sensors 96 controlling temperature and pressure);

passing the blood plasma to screening procedure for filtering (¶ [0111], [0112], DTCs (drip through column) 44 and 46 removing lipids); and

feeding the blood plasma back to the blood after the filtering step (¶ [0031], [0086], returning plasma to patient).

Regarding a step of carrying out flushing with saline solution, Examiner notes that Bomberger does not explicitly disclose using saline solution. However, saline is notoriously used in the extracorporeal fluid treatment arts, since it is biocompatible and does not interfere with filtering processes. Therefore, it would have been obvious to one

of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger as discussed by using saline in a flushing step in order to use an inert or harmless substance.

20. Regarding claim 2, Bomberger discloses a separating step comprising a stepwise separation process for separating the blood plasma at about 150-250 milliliters of blood plasma each time (¶ [0174], plasma batch for treatment by solvent extraction typically about 250 milliliters). It is the Examiner's position that a volume of about 250 ml would have been produced previously by stepwise separation in order to produce a "batch."

21. Regarding claim 3, Bomberger discloses an in-vitro blood plasma lipids screening procedure wherein blood plasma passes to the screening procedure at a speed of 20-30 milliliters per minute (¶ [0124], plasma flow rate between about 10-60 mL per minute).

22. Regarding claim 4, Bomberger discloses the invention as substantially claimed, see above. Bomberger discloses pressure sensors 146, 154 and 156 as discussed above for claim 14. However, Bomberger is silent to the specific pressure of the system being controlled to remain below 60 kPa. However this pressure is deemed a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Regarding rationale and motivation, see discussion of claim 14 above.

23. Regarding claim 5, Bomberger discloses the invention as substantially claimed, see above. Bomberger discloses sensors 96 for monitoring temperature as discussed

for claim 15 above. However, Bomberger is silent to the specific temperature of the system being controlled to remain below 38C. Regarding rationale and motivation, see discussion of claim 16 above.

24. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809) in view of Matkovich et al. (US Patent 5,252,222).

25. Regarding claim 6, Bomberger discloses a first film is a membrane which has filter aperture pore of about 0.3 to 0.65 microns and comprises a lipid absorptive material (¶ [0101]-[0102] and Fig. 3, HFC 18 comprising hollow fibers 20 having pores 26 sized up to 300 nm, or 0.3 μm). Hollow fibers are substantially lipid absorptive, as indicated by their ability to allow lipids to diffuse through pores 26.

Bomberger discloses the invention as substantially claimed, see above. However, Bomberger lacks second and third films as claimed [claim 6]. Matkovich discloses second and third films as discussed for claim 17 above. Regarding rationale and motivation, see discussion of claim 17 above.

26. Regarding claim 7, Bomberger discloses the invention as substantially claimed, see above. However, Bomberger lacks second and third films as claimed [claim 7]. Matkovich discloses second and third films as discussed for claim 17 above. Regarding rationale and motivation to place the first film as taught by Bomberger between second and third filters of Matkovich, see discussion of claim 18 above.

27. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger et al. (US Patent Application Publication No. 2003/0150809) in view of Matkovich et al. (US Patent 5,252,222), further in view of Foltz et al. (US Patent 5,401,466).

28. Regarding claim 8, Bomberger in view of Matkovich discloses the invention as substantially claimed, see above. However, Bomberger in view of Matkovich lacks silicon oxide pellets as claimed [claim 8]. Matkovich discloses a lipid absorptive material comprising silicon oxide pellets as discussed for claim 19 above. Regarding rationale and motivation, see discussion of claim 19 above.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Malchesky; Paul S. et al. US 4350156
- Seidel; Dietrich et al. US 4923439
- Bomberger; David C. et al. US 7033500
- Bomberger; David C. et al. US 7195710
- Bomberger, David C. et al. US 20040256307
- West, III; Glenn et al. US 4781871
- Brugger; James et al. US 5776091

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-

2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764